The opinion in support of the decision being entered today was **not** written for publication in and is **not** binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

JUN 2 3 2006

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES Ex parte PETER T. O'HEERON

Application No. 10/646,675

ON BRIEF

Before FRANKFORT, OWENS and FETTING, **Administrative Patent Judges**. FETTING, **Administrative Patent Judge**.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 8, 9 and 18, which are all of the claims pending and under consideration in this application. Claims 15-17 have been restricted by the examiner, but have not been cancelled.

We AFFIRM IN PART, ADD A NEW GROUND OF REJECTION, AND REMAND.

BACKGROUND

The appellant's invention relates to a kit of obturators for use in endoscopic surgery. An understanding of the invention can be derived from a reading of exemplary claim 18, which is reproduced below.

- 18. A medical procedure kit, comprising:
 - (a) at least one disposable, shield-less obturator for use in endoscopic surgery, each said obturator comprising (i) a proximal end where the obturator is grasped, (ii) a distal end having a tip which is used either to cut or to separate the tissue of a patient, (iii) a shaft between the proximal and distal ends, the proximal end and distal ends [sic] and the shaft being formed as a monolithic structure, and (iv) an orientation indicator located near the proximal end which enables a user to determine by touch the relative position of the tip at the distal end; and
 - (b) a case for enclosing said at least one obturator.

PRIOR ART

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Johnson	5,118,297	Jun. 2, 1992
Vidal et al. (Vidal)	5,405,328	April 11, 1995
Metcalf et al. (Metcalf)	5,453,094	Sep. 26, 1995

In addition, we make the following references of record:

Burchette, Jr. (Burchette) 5,057,082 Oct. 15, 1991 (Burchette is incorporated by reference within Metcalf)

Hickle et al. (Hickle) US2003/0074223 Apr. 17, 2003

REJECTIONS

Claims 18 and 8 stand rejected under 35 U.S.C. § 102(b), or, in the alternative, under 35 U.S.C. § 103, as being unpatentable over Vidal.

Claims 18 and 9 stand rejected under 35 U.S.C. § 103, as being unpatentable over Johnson in view of Metcalf.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the examiner's answer (mailed January 31, 2006) for the examiner's reasoning in support of the rejections, and to appellant's brief (filed October 26, 2005) and reply brief (filed March 6, 2006) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations that follow.

Claim Construction

The examiner and the appellant have differing views on 2 of the limitations in claim 18.

 The appellant argues (Brief, p. 12) that the limitation of an obturator for use in endoscopic surgery has patentable weight as a structural limitation of the shield-less obturator, when contrasted with the obturator of Johnson, which is for use in an endodonic filler application, i.e. a root canal procedure. The appellant further argues that this distinction is supported by the claim limitation that the obturator has a distal end with a tip that is used either to cut or separate tissue. The examiner argues (Answer p. 11) that this phrase is of no patentable moment because in order to further limit the claim there must be some distinction based upon the intended use recited. The examiner further argues that, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

2. The appellant argues (Brief p. 10) that the limitation of the shaft being formed as a monolithic structure is a structural limitation. The examiner argues (Answer p. 9) that the limitation is a product by process limitation because the claim phrase "being formed as" is a manner in which a series of operations, actions, functions or steps proceeds.

With regard to the first claim construction issue, use for endoscopic surgery, we first note that functional limitations in an apparatus claim are met by prior art if the structure shown in the art inherently has the capacity to perform that function. *In re Schreiber*, 128 F.3d 1473, 44 USPQ2d 1429 (Fed Cir 1997). Endoscopic surgery itself requires cutting or separation of tissue to make the portion of the anatomy to be subjected to endoscopic surgery accessible. The specification at p. 2, Vidal at col. 1, lines 32-35 and Metcalf col. 1, lines 30-33 all teach that an obturator, as used in endoscopic surgery, is, and therefore must be capable of being, placed in a bore

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(referred to as the lumen or access tube) in a trocar and used in cutting or separating tissue.

Therefore, the claim limitation of use in endoscopic surgery adds structural narrowing to the claimed obturator in that the obturator must have a structure which is capable of fitting in a trocar and of cutting or separating tissue.

With regard to the second claim construction issue, the claim explicitly requires that the proximal end, distal ends and the shaft are formed as a monolithic structure. While it is true that, as the examiner asserts, this means that the formation process must be such as to make the obturator monolithic, this limitation affects the scope of the resultant structure at least as much as the process that achieves that structure. That is, the claimed "being formed as" implies being formed to result as, and so we conclude the claimed obturator must structurally be monolithic.

Having resolved the claim construction issues, we now turn to the rejections.

Claims 18 and 8 stand rejected under 35 U.S.C. § 102(b), or, in the alternative, under 35 U.S.C. § 103, as being unpatentable over Vidal.

As noted above, the limitation of "the proximal end and distal ends [sic] and the shaft being formed as a monolithic structure" is a structural limitation. None of the obturators taught by Vidal are monolithic, but instead are comprised of multiple parts. This includes the prior art obturators that have a safety shield, because the safety shield negates any otherwise monolithic character of the obturator.

Accordingly, we do not sustain the rejection of claims 18 and 8 under 35 U.S.C. § 102(b) as being unpatentable over Vidal.

We note that the examiner asserted an alternate rejection under 35 U.S.C. § 103 (Answer p. 4). The examiner argued (Answer p. 10) that one of ordinary skill in the art would have been motivated to form an obturator as a monolithic structure so as to make what is separate, integral, which makes for ease of assembly and use. The appellant has not argued or provided any evidence that one of ordinary skill would not have had such a motivation to form an obturator as a monolithic structure and therefore the examiner's statement of essentially notoriously well known construction techniques is sufficient evidence to meet the burden of establishing this element of the claim 18 subject matter¹.

The appellant argues (Brief p. 11) that Vidal fails to show the claim limitation of an orientation indicator located near the proximal end which enables a user to determine by touch the relative position of the tip at the distal end. The examiner responds (Answer p. 4 and 8) that defining a raised surface at the proximal end is manifestly capable of functioning as an orientation indicator, and enables a user to determine by touch the relative position of the tip at the distal end. To this, the appellant responds (Reply Brief p. 3) that the difference in diameters is substantially the same for all points around the circumference of the shaft and handle and the only information that can be obtained by touch from this difference in diameters is that a change in diameter exists near the most proximal part of the obturator.

¹ We note that Metcalf, applied in the other rejection under 35 U.S.C. § 103 in this appeal, is issued to the same assignee, Minnesota Mining and Manufacturing Company, with one inventor, i.e. Gerald L. Metcalf, in common with Vidal. Fig. 4 of Metcalf shows a monolithic obturator for use in endoscopic surgery, supporting the examiner's assertion that monolithic obturators would be within the capacity of one of ordinary skill in the art.

From this exchange we surmise that the appellant is arguing that Vidal shows no indicator such that one can know the axial rotation degree along the axis of the shaft (Reply Brief p. 4), whereas the examiner is arguing that the claim is more broad. We note in particular that the phrase "the relative position of the tip" contains no criterion from which to measure the relative position, i.e. the position may be relative to anything. Although not explicitly stated by the examiner, we surmise the examiner's arguments suggest that the tip position, as argued by the examiner, is relative to three dimensional space, for surely, a grip on the raised surface of the Vidal obturators enables a user to determine in which direction the tip is pointing in three dimensional space.

The absence of an explicit limitation on what the relative position is relative to results in a claim of broader scope than that which the appellant argues, and such a broader scope encompasses a relative position as argued by the examiner.

Because this is the only limitation argued by the appellant against the rejection under 35 U.S.C. § 103 over Vidal, we **sustain** the examiner's rejection of claim 18 under 35 U.S.C. § 103 over Vidal.

The appellant has argued that claim 8 is patentable because its underlying claim 18 is patentable and has provided no separate arguments for patentability of claim 8. Accordingly, claim 8 falls with claim 18 and we similarly **sustain** the rejection of claim 8, although we make no opinion regarding the merits that might have been presented regarding the separate patentability of claim 8.

Claims 18 and 9 stand rejected under 35 U.S.C. § 103, as being unpatentable over Johnson in view of Metcalf

The appellant argues that Johnson does not show an obturator for use in endoscopic surgery. As we discussed in claim construction above, to be for use in endoscopic surgery, an obturator must be capable of being placed in a bore (referred to as the lumen or access tube) in a trocar and of cutting or separating tissue. We note that dental obturator is structurally similar to an endoscopic obturator, differing primarily in size. Obturators used in endoscopic surgery and in dentistry as portrayed in Metcalf and Johnson have the same structural characteristics as in the appellant's claims, i.e. they have proximal ends designed for grasping and distal ends with a tip, and with a shaft connecting the two ends and an enlarged circumference at the grasping end that provides orientation information relative to the tip, at least in three dimensional space.

Both references have at least one embodiment in which the tip is blunt [compare Johnson fig. 1 and Metcalf col. 3 lines 64-67].

Associated with this argument of use in endoscopic surgery, the appellant argues [See Brief p. 12; Reply Brief, p. 6] that the tip of a dental obturator is not used to cut or separate tissue because it is covered with a filler material and designed to be inserted in a pre-drilled canal in a tooth. The examiner argues (Answer p. 11) that such an insertion is a cutting or separation of tooth tissue by virtue of such an insertion into such tissue. Johnson's blunt tip is capable of separating tissue as taught in the background as filling and entombing, thus separating, the pulpal material (tissue) remaining in the tooth. [See col. 1 lines 39-48]

Thus, we find that the appellant's arguments that the examiner failed to present a prima facie case are unpersuasive and we **sustain** the examiner's rejection of claim 18.

The appellant has argued that claim 9 is patentable because its underlying claim 18 is patentable and has provided no separate arguments for patentability of claim 9. Accordingly, claim 9 falls with claim 18 and we similarly **sustain** the rejection of claim 9, although we make no opinion regarding the merits that might have been presented regarding the separate patentability of claim 9.

New Grounds of Rejection Under 37 CFR § 41.50(b)

Pursuant to 37 CFR § 41.50(b), we enter the following new ground of rejection:

Claims 18 and 8 are rejected under 35 U.S.C. § 102(b) as being unpatentable over Metcalf, which fully incorporates the contents of Burchette by reference [See Metcalf col. 5 lines 40-48].

Metcalf's Fig. 4 and corresponding description at col. 5 lines 14-16, especially as contrasted with its Fig. 5 and corresponding description at col. 5 lines 31-33, portray a monolithic obturator with a pointed distal end for cutting tissue and an enlarged circumference proximal end for grasping, and which enlarged circumference enables the holder to apprehend the orientation of the tip in three dimensional space relative to the grasped end. Metcalf shows a kit of such obturators. [See Fig. 1] As further textual evidence of this anticipation, Burchette, fully incorporated by reference within Metcalf, teaches an obturator that

is preferably a **unitary**, **one-piece structure** made of polymeric material, either thermoplastic or thermoset and from a process which results in the final manufacture as a single article of manufacture. Examples of suitable polymeric materials include, without limitation,

nylons, polyacetals, and polycarbonates. As shown in FIG. 2, the mandrel 16 is formed with a main shank portion 18, a knob-type handle 20 at one end, and at the distal end a piercing and cutting end 22. The knob 20 is made integral with the shank 18 and having an outer surface 24 of suitable shape for the palm of the user. The knob 20 is made of a larger diameter than the shank 18 to permit the insertion of the shank 18 between the user's fingers for easy withdrawal of the obturator. [See col. 3 lines 22-36] (emphasis added)

As to claim 8, the kit shown by Metcalf [See Fig. 1 and col. 3 lines 59-67] includes at least one embodiment of each of the three claimed styles of tips. We note that claims 18 and 8 only require that at least one of the obturators in the kit meet the monolithic structural limitations of claim 18.

REMAND TO EXAMINER

Pursuant to our authority under 37 CFR § 41.50(a)(1), we remand this application to the Examiner to consider rejecting claim 9 over Metcalf, which fully incorporates the contents of Burchette by reference, in view of Hickle.

Claim 9 depends from claim 18, the rejection of which under Metcalf, which fully incorporates the contents of Burchette by reference, is shown above. Claim 9 further adds the limitations of graphical and/or textural information that can assist in matching an obturator with a trocar. As with claims 18 and 8, claim 9 is an apparatus claim, and so the limitation regarding such assistance goes only to the structural capacity to provide such assistance, and not to an actual performance of such assistance.

Hickle shows encoding information related to medical supplies and kits, the information being marked on such supplies [See para. 2 and 11] and relates this to medical supplies used in endoscopic surgery [See para. 5] where the information is used to ensure proper form, fit and function [See para. 7].

CONCLUSION

To summarize:

- The decision of the examiner to reject claims 18 and 8 under 35
 U.S.C. § 102(b) as being unpatentable over Vidal is not sustained.
- The decision of the examiner to reject claims 18 and 8 under
 35 U.S.C. § 103, as being unpatentable over Vidal is sustained.
- The decision of the examiner to reject claims 18 and 9 under
 35 U.S.C. § 103, as being unpatentable over Johnson in view of Metcalf is sustained.
- A new ground of rejection rejecting claims 18 and 8 under 35
 U.S.C. § 102(b) as being unpatentable over Metcalf, which fully incorporates the contents of Burchette, is newly entered.
- The appeal is remanded to the examiner to consider the applicability of
 Hickle toward the issue of patentability of claim 9 when combined with the
 teachings of Metcalf, which fully incorporates the contents of Burchette.

Regarding the affirmed rejection(s), 37 CFR § 41.52(a)(1) provides "[a]ppellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection of one or more claims, this opinion contains a new ground of rejection pursuant to 37 CFR § 41.50(b) and a remand pursuant to 37 CFR § 41.50(e) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)).

37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." 37 CFR § 41.50(e) provides that

[w]henever a decision of the Board includes a remand, that decision shall not be considered final for judicial review. When appropriate, upon conclusion of proceedings on remand before the examiner, the Board may enter an order otherwise making its decision final for judicial review.

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

- (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
- (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

The effective date of the affirmance is deferred until conclusion of the proceedings before the examiner unless, as a mere incident to the limited proceedings, the affirmed rejection is overcome. If the proceedings before the examiner do not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejections, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 103 1.136(a)(1)(vi).

AFFIRMED IN PART NEW GROUND OF REJECTION UNDER 37 CFR § 41.50(b) REMAND TO EXAMINER UNDER 37 CFR § 41.50(a)(1)

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Administrative Patent Judge

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